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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,964	04/15/2004	Kenneth T. Heruth	1023-360US01	8232

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,964	HERUTH ET AL.	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-33 and 35-71* is/are pending in the application.

4a) Of the above claim(s) *1-18,46-52 and 63-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-33,35-45,53-62 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/2/07; 7/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on February 20, 2007. The Examiner acknowledges the amendment of claims 25, 53-57 and 60; and the addition of claims 69-71. Claims 1-33 and 35-71 are pending, with claims 1-18, 46-52 and 63-68 withdrawn from consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 19-26, 28, 29, 32, 33, 38-45, 53-58, 62 and 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Poezevera (U.S. Patent Number 6,890,306).

In regard to claims 19-26, 53-56 and 69-71, Poezevera discloses an active medical device for the diagnosis of the sleep apnea syndrome. The medical device disclosed by Poezevera comprises a plurality of sensors. Each sensor generates a signal as a function of at least one physiological parameter of a patient (col. 3, lines 49-67; col. 4, lines 1-39). The device also includes an implantable device and a microprocessor with memory. The microprocessor monitors a plurality of physiological parameters of the patient based on the signals output by the sensors (col. 5; col. 6, lines 1-62). The Poezevera device determines a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters. The value if the

sleep metric ranges between about 0 to about 1. Poezevera discloses using the device to monitor respiratory rates and blood oxygen saturation levels of a patient. The microprocessor disclosed by Poezevera determines variability and a mean value of at least one of the physiological parameters and determines sleep metric values from the information gathered (col. 4; col.5; col. 6, lines 1-42). The system then determines a value of an overall sleep metric based the values of the plurality of sleep metrics and determines the value of the overall sleep metric by averaging the values of the plurality of sleep metrics.

In regard to claims 28, 29, 32, 33, 38-45, 57, 58 and 62, Poezevera discloses a device further including a memory used to store threshold values, wherein the processor compares the value of the sleep metrics to the threshold values and determines whether the patient is asleep based on the comparison (col. 3, lines 49-67; col. 4; col. 5; col. 6, lines 1-52). Poezevera discloses a means for monitoring a plurality of physiological parameters of a patient and a means for determining a value of a sleep metric indicates based on the physiological parameters. The Poezevera device further includes a means for generating at least one signal as a function of the physiological parameters, wherein the means for monitoring comprises means for monitoring the physiological parameters based on the signal. The means for determining a sleep metric expressed by Poezevera comprises means for determining a value for each of a plurality of sleep metrics, each of the plurality of values determined based on a respective one of the physiological parameters (col. 4-6). The Device determines a value of a sleep metric by determining a value of an overall sleep metric based the values of the plurality of sleep metrics and a comparison of the value of the sleep metric to a threshold value. Additionally, Poezevera discloses a means for delivering a therapy to the patient and means for controlling delivery of a therapy to the patient

by the therapy delivery means based on the determination of whether the patient is asleep (col. 6, lines 1-58). The Poezevera device has a storage mechanism for storing values to access at a later time. Poezevera suggests the implantable medical device may be an implantable neurostimulator (col. 3, lines 55-67).

4. Claims 19-21, 23-31, 35-37, 59-61 and 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (U.S. Patent Application Publication Number 2004/0111040). In regard to claims 19-21, 23-31, 35-37, 59-61 and 69-71, Ni et al. disclose a device, which detects disordered breathing in a patient. The Ni et al. device includes a binary sleep detector for determining the sleep state of the patient, allowing the breathing pattern to be monitored during a sleep state of the patient. The device disclosed by Ni et al. includes a microprocessor with memory and a plurality of sensors for generating a signal as a function of a physiological parameter of a patient (paragraphs [0051]-[0057]). The sensors are able to monitor heart rate, pulse oximetry, blood pressure, body temperature and other physiological parameters as selected by the user. Ni et al. disclose having the processor determine the mean and a weighting factor in determining the sleep metrics for a patient (paragraphs [0041]-[0047]). The processor also compares the sleep metrics gathered to a threshold value stored in memory to determine a sleep state of the patient. The Ni et al. device includes an eye movement sensor which determines the sleep state of the patient (paragraph [0051]-[0061]). Ni et al. further suggest the implantable medical device could include an implantable sensor or the implantable medical device could be coupled to the sensor via a lead or wireless communication.

Response to Arguments

5. Applicant argues the prior art references fail to disclose an implantable device, which returns a sleep metric indicating a probability of a patient being asleep. Examiner respectfully disagrees. Examiner submits the Poezevera and Ni et al. prior art references both provide an indication whether or not the patient is asleep. Any binary indicator of the sleep state of a patient meets the limitations as set forth in the claim since binary metrics provide probability information as recited in claim language. Applicant's arguments filed February 20, 2007 have been fully considered but they are not persuasive. The rejection stands.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

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